REMARKS

Claims 1 and 3-13 are all the claims pending in the application, prior to the present Amendment.

The Examiner has attached to the Office Action a copy of the PTO/SB/08 Form filed with the Information Disclosure Statement of July 14, 2006. The Examiner has initialed and dated this Form to indicate that he has considered and made of record all of the documents listed on this Form, except that the Examiner has continued to cross off the Letunova et al article.

In the Office Action, the Examiner states that he has now considered and made of record JP 49-55629, because it corresponds to the three U.S. patents listed on that form, but that he continues to not consider the Letunova et al article because it is not in the English language.

The Examiner states that the fact that the Letunova et al article was cited in the International Search Report is an insufficient basis upon which the Examiner can consider and make of record a non-English language document.

Applicants disagree with the Examiner in his refusal to cite the Letunova et al article. The Examiner does not appear to be aware of or understand the relevant portions of the MPEP which specifically state that the submission of an International Search Report is a sufficient statement of relevance.

Thus, the MPEP at 609.04(a) contains the following statement.

> 1. Where the information listed is not in the English language, but was cited in a search report or other action by a foreign patent office in a counterpart foreign application, the requirement for

> a concise explanation of relevance can be satisfied by submitting an English-language version of the search report or action which indicates the degree of relevance found by the foreign office. This may be an explanation of which portion of the reference is particularly relevant, to which claims it applies, or merely a "X", "Y", or "A" indication on a search report.

Thus, the MPEP clearly states that the submission of the Search Report is a sufficient concise statement of relevance.

The ISR indicates that the Letunova et al document is a "Y" document and is relevant to claim 4.

Moreover, applicants in this case relied not only on the International Search Report, but also relied on the Written Opinion of the International Searching Authority for all of the submitted references. The Written Opinion of the International Searching Authority cites the Letunova et al document as Document 4, and contains a discussion of Document 4 as it relates to claim 10. The Written Opinion states that "Document 4 describes that 5-hydroxy-pentanone can be acquired from 2-acetyl-γ-butyrolactone (Document 4: page 121). It is obvious for an expert in the relevant technical field to produce 5-hydroxy-pentanone by acid-hydrolyzing 2-acetyl-γ-butyrolactone. Besides a person skilled in the art could have easily employed 5-hydroxy-pentanone produced as a material for producing the optically active 1,4-pentanediol described in documents 1 to 3."

In view of these disclosures, applicants submit that it is clear that the Examiner should have made of record and considered the Letunova et al document. Accordingly, applicants again request the Examiner to consider and make the Letunova et al article of record.

Further, to the extent that the Examiner states that he has considered JP 49-55629 in view of the corresponding listed U.S. patents, applicants point out that the International Search Report and the Written Opinion also cite and discuss this JP reference. Accordingly, in view of the MPEP, the Examiner should have considered this JP reference for these additional reasons.

The Examiner sets forth a statement relating to double patenting that does not set forth any rejection of the claims under double patenting. Accordingly, it is not clear why the Examiner referred to double patenting in the Office Action. Applicants request the Examiner to clarify this point.

The Examiner states that if claim 10 is found to be allowable, he will object to claim 13 as being a substantial duplicate of claim 10. The Examiner states that claim 13 is clearly the combination of the recitations of claims 10 and 1, and that despite a slight difference in wording, the claims are substantially duplicates.

Applicants disagree with this statement of the Examiner.

Claim 1 requires the use of an enzyme source to stereoselectively reduce the 5-hydroxy-2-pentanone. Claim 10, which depends from claim 1, therefore, also requires the use of an enzyme source. On the other hand, claim 13 does not refer to the use of an enzyme source. Claim 13 has a different scope than claim 10, and is not a substantial duplicate of claim 10.

The Examiner states that he has withdrawn the previous rejection of claim 1 as anticipated under 35 U.S.C. § 102(b) by the Whitney et al article, which the Examiner cites as appearing in *Advances in Chemistry*, Vol. 130:270-80 (1972). This citation by the Examiner is in error. The Whitney et al article in *Advances in Chemistry* is a 1974 document, and not a 1972 document. In the previous Office Action, the Examiner correctly referred to the Whitney et al document as being a 1974 document, but now for some unknown reason refers to it as being a 1972 document. There is another Whitney et al document that has been cited that was published in 1972, but this is not the document that was employed in the previous rejection or in the following new rejection where the Examiner relies on page 277 of the Whitney et al article. Page 277 appears in the 1974 Whitney et al document, and not in the 1972 Whitney et al document.

Claim 1 has been newly rejected under 35 U.S.C. § 102(b) as anticipated by Whitney et al, *Advances in Chemistry*, Vol. 130: 270-280 (correctly 1974).

Applicants submit that Whitney et al (1974) do not disclose or render obvious the subject matter of claim 1 and, accordingly, request withdrawal of this rejection.

The Examiner states, at the bottom of page 5 and page 6 of the Office Action, that Whitney et al, at page 277, teach the reduction of 5-hydroxy-2-pentanone by chelated lithium compounds to yield optically active 1,4-pentanediol. The Examiner states that the compounds exhibit stereoselective reduction, otherwise the resultant compound would not be optically active. The Examiner states that the claim, therefore, is anticipated.

The Examiner seems to have become confused by the requirements of the present claims and the teachings of Whitney et al.

Claim 1 clearly recites that the process requires that the asymmetrical reduction occurs by an enzyme source having the activity of stereoselectively reducing the 5-hydroxy-2-pentanone. Whitney et al do not disclose the use of an enzyme source to stereoselectively reduce the 5-hydroxy-2-pentanone of formula (1) to produce the pentanediol of formula (2).

In the previous Office Action, the Examiner did not reject claim 2, which recited the use of an enzyme source, under 35 U.S.C. § 102(b) as anticipated by Whitney et al. Applicants amended claim 1 to incorporate the recitations of claim 2. The Examiner seems to have overlooked this point.

Further, applicants have amended claim 1 to incorporate the recitations of claim 9. Claim 9 has not been rejected over Whitney et al.

In view of the above, applicants submit that Whitney et al do not disclose or render obvious the subject matter of claim 1 and, accordingly, request withdrawal of this rejection.

Claims 1, 10 and 13 have been rejected under 35 U.S.C. § 103(a) as obvious over the 1974 Whitney et al article and the general knowledge in the art.

Applicants submit that Whitney et al (1974) do not disclose or render obvious the subject matter of claims 1, 10 and 13 and, accordingly, request withdrawal of this rejection.

In this rejection, with respect to claims 1 and 10, the Examiner argues that Whitney et al teach one form of enzymatic reduction of the compound. As applicants discussed above, the Examiner has misanalyzed the Whitney et al article because it does not show the enzymatic

reduction of the compound of formula (1) to produce the compound of formula (2). For this reason alone, applicants submit that claims 1 and 10 are patentable over Whitney et al.

Further, claim 1 now recites the specific enzyme sources of claim 9 that are not disclosed by Whitney et al. Claim 9 was not subject to this rejection. Accordingly, claim 1, as amended above, and claim 10, which depends from claim 1, are clearly patentable over Whitney et al.

With respect to claim 13, this claim 13 does not recite the use of an enzyme source, but is directed to a method which comprises hydrolyzing 2-acetyl-gamma-butyrolactone of formula (5) in the presence of an acid to produce the 5-hydroxy-2-pentanone compound of formula (1), and asymmetrically reducing the 5-hydroxy-2-pentanone compound of formula (1) to obtain the optically active 1,4-pentanediol of formula (2). Thus, claim 13 employs 2-acetyl-gamma-butyrolactone as the source of 5-hydroxy-2-pentanone of formula (1) when asymmetrically reducing the 5-hydroxy-2-pentanone of formula (1) to optically active 1,4-pentanediol represented by formula (2).

Whitney et al do not disclose or suggest employing 2-acetyl-gamma-butyrolactone as the source of 5-hydroxy-2-pentanone when asymmetrically reducing 5-hydroxy-2-pentanone to optically active 1,4-pentanediol represented by formula (2).

The Examiner states that 2-hydroxy-gamma-butyrolactone (correctly, 2-acetyl-gamma-butyrolactone) is a known compound that has been available for years, and that applicants' specification teaches (at page 8) that the availability of 2-hydroxy-gamma-butyrolactone (correctly, 2-acetyl-gamma-butyrolactone) is superior "to other sources" which, according to the Examiner, evidences applicants' acknowledgement of the state of the prior art. The Examiner

takes Official Notice that it is well known that 2-hydroxy-gamma-butyrolactone (correctly, 2-acetyl-gamma-butyrolactone) has been available for years.

Although the present specification teaches that 2-acetyl-gamma-butyrolactone is easily available, it does not indicate that it can be used to form 5-hydroxy-2-pentanone.

The Examiner states that one of ordinary skill in the art would instantly recognize that an acid hydrolysis of this compound (correctly, 2-acetyl-gamma-butyrolactone), followed by a reduction with LiAlH4, will yield the alcohol of formula (2).

Even if one of ordinary skill in the art would recognize that such a reaction would take place, this does not mean that one of ordinary skill in the art would employ the 2-acetyl-gamma-butyrolactone as the source of the 5-hydroxy-2-pentanone of formula (1) when reacting it to form the alcohol of formula (2).

The present specification discloses that the use of the 2-acetyl-gamma-butyrolactone of formula (5) avoids the problem that when the compound of formula (1) is stored at a high concentration, the purity thereof may be decreased because of dehydration condensation by itself. Whitney et al do not disclose or suggest any method to avoid this problem, and do not disclose that the problem exists.

In response to applicants' argument that the use of this compound avoids degradation and, therefore, its use is unobvious, the Examiner states that he is relying on this compound for reasons that are not the same as applicants', and that his reliance on the compound does not have to be the same as applicants in view of *KSR v. Teleflex*. The Examiner states that the motivation

to employ the compound is the fact that it is available, and would be instantly understood to be able to make the compound for reduction.

The *KSR* case indicates that applicants can rely on unexpected results to overcome an obviousness rejection. The mere fact that the compound was available does not indicate that one would recognize that problems can be overcome by its use. Accordingly, applicants submit that the use of the compound provides unexpected results and supports the patentability of claim 13.

Further, the Examiner's position that merely because a compound is known indicates that it would be obvious to use that compound in a process is contrary to the well-established law that a new use for an old product can be patented in the form of a process claim. The Examiner's position leads one to the unsupportable conclusion that any claim directed to a new synthesis method could not be patented as long as there existed an already known compound that could be used in the method. As stated in *KSR*, "... a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art." [emphasis added]

Process claims generally are directed to one or a series of steps that employ one or more known materials in a new way, and patentability can be based on the fact that the steps themselves are not shown or suggested in the prior art, or on the fact that use of the material in the claimed process is not shown or suggested in the prior art. If the result of the process is unobvious and the particular use of the material is not suggested by the prior art, the process claim is patentable. *Ex parte Wagner*, 88 USPQ 217, 220 (Pat. Off. Bd. App. 1950). Such is the case here.

In view of the above, applicants submit that claims 1, 10 and 13 are patentable over Whitney et al and, accordingly, request withdrawal of this rejection.

Claims 1-3, 7-10 and 13 have been rejected under the first paragraph of 35 U.S.C. § 112 as being based on a non-enabling disclosure.

The Examiner states that the closest prior art with regard to biochemical reductions are the two Wada et al articles, one of which is newly cited.

The Examiner asserts that applicants have argued that several substrates will not work with specific enzymes, and there is simply no way to reasonably predict which of the enzymes or which other enzymes will produce the activity required for reducing pentanones with the stereoselectivity required. The Examiner states that the present specification broadly teaches many sources of enzymes, and broadly states that these enzymes may be used to obtain various isomers with the various stereoselectivity.

The Examiner states that the present specification discloses examples which teach encoded deposits of enzymes pNTS1G, pNTFPG, pNTDRG1, pNTRS, and pNTRGG1, without reference to which enzyme is which, and from where it is obtained. The Examiner states that he therefore, cannot determine what specific enzymes will work.

The Examiner further states that it is clear from the specification that the enzyme source is self-determining, and that there is no more elaborations in the specification to which enzyme sources actually have the activity.

The Examiner argues that, therefore, undue experimentation would be required to practice the invention.

In response, applicants have amended claim 1 to direct it to the enzyme sources recited in claim 9, which are specific enzyme sources. These enzyme sources are described in the specification in paragraph [0054], beginning at page 18 of the specification. Example 1, as shown in Table 1, employed the enzyme sources of claim 9. Applicants submit that claim 1 as amended above is clearly enabled by the specification, especially in view of the disclosures at paragraph [0054] and Example 1.

With respect to claim 13, it does not recite enzyme sources, but recites the step of hydrolyzing the compound of formula (5) in the presence of an acid to produce the compound of formula (1), and then asymmetrically reducing the compound of formula (1) to the compound of formula (2). Since claim 13 does not recite the use of an enzyme source, applicants submit that the Examiner's rejeciton is not applicable to claim 13. The asymmetrical reduction of the compound of formula (1) to the compound of formula (2) is known in the art, as shown by the 1974 Whitney et al article.

In view of the above, applicants submit that the present claims are based on an enabling disclosure and, accordingly, request withdrawal of this rejection.

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,

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